K072906

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Home SkinovationsLtd.

Silk'n

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

JAN 23 2008

Submitter's information

Name:	Home Skinovations Ltd.
Address:	Apolo building, POB 533, Yokneam 20692, Israel
Contact:	Dr. Amir Waldman VP Regulatory Affairs

Device information

Trade/Proprietary name:	Silk'n
Common/Usual name:	Light based hair removal device
Classification name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (21CRF §878.4810)
Product code:	GEX

Predicate devices

- ABC hair removal system, (K060839)
  Palomar Medical Technologies Inc.
- SpaTouch Photoepilation system, (K020856)
  Radiancy Ltd.

Intended use:

The Silk'n is intended for removal of unwanted hair by using selective photothermal treatment. The device is generally indicated for dermatological use. The Silk'n is specifically indicated for patient removal of unwanted hair by using selective photothremal treatment under the direction of a physician, after training by a healthcare professional.

Device Description:

The Silk'n hair removal system is composed of a base unit and hand held applicator. Details are provided in the chapter 1: Device description, of this submission.

Performance & clinical data:

The device complies with the following U.S. Food and Drug Administration performance standards: 21CRF § 1040.10 & 1040.11. Clinical data was collected in a prospective clinical study to support the safety and effectiveness of the Silk'n hair removal device. The clinical studies demonstrated that the Silk'n system functions as intended with no adverse events.

Substantial Equivalence:

The Silk'n system is substantial equivalent to its predicate devices. The data in this 510k submission demonstrate that the Silk'n system shares the same intended use and similar overall characteristic, therefore is substantial equivalent to its predicate devices. Details are provided in chapter 3: Substantial equivalent of this submission.

Based upon an analysis of the overall performance characteristic for the device, Home Skinovations Ltd. believes that no significant differences exit. Therefore the Silk'n should raise no new issues of safety or effectiveness.

January 11, 2008

Date

Dr. Amir Waldman,
VP Regulatory Affairs
Home Skiovations Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2008

Home Skinovations, Ltd.
% Dr. Amir Waldman
VP Regulatory Affairs
Apolo Building, POB 533
Yokneam 20692
Israel

Re: K072906
Trade/Device Name: Silk'n
Regulatory Number: 21 CFR 878.4810
Regulatory Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 11, 2008
Received: January 17, 2008

Dear Dr. Waldman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known)_____.

Device Name___Silk'n.

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___X__ OR Over The Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K072906